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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/713,732

11/14/2003

Peter Palese

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3723

20583

7590

10/24/2006

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

MOSHER, MARY

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,732

Applicant(s)

PALESE ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-7,11-13,16-18,21-25,27-29,33-35,38-40,43-46 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) 7,13,18,29,35 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,11,12,16,17,21-25,27,28,33,34,38,39 and 43-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/14/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of species influenza in the reply filed on 10/6/2006 is acknowledged. The traversal is on the ground(s) that search of all species would not be unduly burdensome. This is not found persuasive because each species of virus requires separate search and consideration to determine if prior art viruses inherently meet the claim limitations, which constitutes an undue burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7, 13, 18, 29, 35, 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/6/2006.

Claims 1, 3, 5, 6, 11, 12, 16, 17, 21-25, 27, 28, 33, 34, 38, 39, 43-46, 49-51 have been examined. Claims 1, 3, 11, 16, 23-25, 33, 38, 49-51 have been examined only to the extent that they read upon the elected influenza virus group.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 5, 6, 11, 12, 16, 17, 21-25, 27, 28, 33, 34, 38, 39, 43-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,669,943. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the previously patented subject matter.

Claims 1, 3, 5, 6, 11, 12, 16, 17, 21-25, 27, 28, 33, 34, 38, 39, 43-46, 49-51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,866,853. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the previously patented subject matter.

Claims 1, 3, 5, 6, 11, 12, 16, 17, 21-25, 27, 28, 33, 34, 38, 39, 43-46, 49-51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-9 U.S. Patent No. 6,468,544. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the previously patented subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 6, 11, 12, 16, 17, 21-25, 27, 28, 33, 34, 38, 39, 43-46, 49-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Butterfield et al (Am. J. Vet. Res. 1978. Vol. 39. No. 4. pages 671-674). Butterfield et al teaches a vaccine formulation comprising an attenuated influenza virus A/Turkey/Oregon/71, and a method comprising administering the composition to a subject. Although Butterfield does not explicitly teach that A/Turkey/Oregon/71 has an interferon antagonist phenotype that is responsible for attenuation and permits the attenuated virus to grow to higher titers in interferon-deficient host systems, this phenotype is an inherent characteristic of the virus. As evidence that the vaccine of Butterfield necessarily and inherently meets each and every limitation of the product claims, see specification page 18, line 38, through page 19, line 1; or see Norton et al (Virology. 1987. Vol. 156. pages 204-213), which teaches that the virus incorporated in the vaccine of Butterfield et al inherently contains a truncation of the C-terminus of the NS1 protein. In addition, although the reference virus was not produced by genetic engineering methods, a virus identical to the reference virus could be produced by genetic engineering, therefore claims 3 and 25 encompass a virus formulation identical to that disclosed in the reference. Therefore, although Butterfield does not teach the characteristic of interferon antagonist phenotype, this phenotype is necessarily and inherently a feature of the

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vaccine virus taught by Butterfield. Furthermore, Butterfield administered the formulation to subjects in amounts similar to the doses administered in applicant's working examples of the methods of claims 49-51. Since Butterfield teaches administering the same formulation in the same amounts to subjects, Butterfield meets each and every limitation of the method claims, even though Butterfield may not teach mechanisms and outcomes that inherently result from practice of the method (inducing a cellular interferon response, preventing infectious disease, preventing tumors).

Scheupbach et al (Blood 62:616-621, 1983) is cited as of interest, in teaching a cancer treatment method which comprises administration of a pharmaceutical carrier and cells comprising an avian influenza virus at a dose effective to elicit an immune response.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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October 20, 2006


MARY E. MOSHER, PH.D.
PRIMARY EXAMINER